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09/147,237 04/20/99 YAGI

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EXAMINER

PRATS, F

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

04/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/147,237**

Applicant(s)

**Eiichiro Yagi et al**

Examiner

**Francisco C. Prats**

Group Art Unit  
**1651**



☒ Responsive to communication(s) filed on Jan 27, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) 5-14 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4 and 15-18 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

1. The amendment filed January 27, 2000, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.
2. Claims 15-18 have been added.
3. Claims 1-18 are pending.

***Election/Restriction***

4. Claims 5-14 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. As discussed in the previous office action, election was made **without** traverse in Paper No. 6, filed June 25, 1999.
5. Claims 1-4 and 15-18 are examined on the merits.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

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and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *treating* UV-induced immune suppression, does not reasonably provide enablement for "preventing" or "controlling" UV-induced immune suppression, as currently recited in the newly added method claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Specifically, the claim language "preventing" and "controlling" immunosuppression encompasses avoiding entirely every incidence and/or aspect of the disorder, in a manner such that immune system function is unaffected by UV exposure. It is well known that inflammation and immunosuppression are complicated processes involving various factors which are not entirely understood. Thus, even the best immunosuppressive agents are not 100% successful, as required by the current claim language at its broadest.

Moreover, applicant's own *in vitro* data bears this out. Specifically, applicant discloses that glutathione does not completely restore immune function as currently encompassed the

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claims. See Fig. 1. Thus, in view of the complexity and unpredictability inherent in this art, as well as the lack of an example supporting the full breadth of the claimed subject matter, the skilled artisan would expect to have to experiment unduly to be able to practice the full breadth of the claimed subject matter, and reverse 100% of immunosuppressive events caused by UV radiation. Note specifically that claims reciting -- treating -- immunosuppression would be considered enabled.

8. Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "controlling immunosuppression" in claim 15 renders that claim and its dependents indefinite. Specifically, it is not clear what type of response to the therapeutic steps is encompassed by the claims. That is, to the extent that the preamble provides meaning to the claims, it is not clear what actions or results, other than the claimed steps, are encompassed or necessitated by the claims. A holding of indefiniteness is therefore required. Note that use of the term -- treating -- instead of controlling would overcome this ground of rejection.

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Also, claim 18 is indefinite because the term "the liniment" lacks clear antecedent basis in the claim. Specifically, because the preamble recites an "immunopotentiator" it is not clear that the claim is limited to the "liniment" later recited in the claim.

***Claim Rejections - 35 USC § 102***

9. Claims 1-4 and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hersh et al (U.S. Pat. 5,667,791).

10. Claims 1-4 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuura et al (U.S. Pat. 5,407,667) or Hara et al (U.S. Pat. 5,316,767) or Oyama et al (U.S. Pat. 4,990,330).

11. As amended, the claims recite methods of preventing or controlling immunosuppression caused by UV to the skin, wherein a liniment containing 0.01 to 10 weight % glutathione is contacted with the skin. Each of the cited references discloses the application to skin of glutathione-containing drugs. See Hersh '791 at col. 7 (0.15% glutathione); see also Matsuura '667 at col. 2 (0.2% of a 4.6:17 glutathione: $\beta$ -cyclodextrin inclusion complex, equaling about 0.05411 weight% glutathione in the final

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preparation); see also Hara '767 at col. 9, lines 34-35 (0.001-10% W/W glutathione); see also Oyama '330 at col. 4 (1% glutathione). A holding of anticipation is required.

All of applicant's argument has been fully considered but is not persuasive of error. It is noted, as argued by applicant, that none of the references specifically mentions UV-induced immunosuppression. However, each of the references contacts the claim-designated active ingredient (glutathione) with the claim-designated patient (anyone) on the claim-designated part of the body (the skin). In view of the fact that the prior art methods employ the same active ingredient as that claimed, the prior art methods necessarily possess the protective and/or controlling effects recited in the claims. Thus, the prior methods inherently anticipate the claimed methods.

Moreover, even if the claims were limited to treatment methods, each of Matsuura and Hara disclose that the glutathione-containing compositions are employed as skin "whiteners" in response to sun exposure, the exact patient disclosed by applicant as being the recipient of the claimed treatment. Further still, Oyama explicitly discloses that the glutathione-containing compositions are useful in combating UV-induced skin injury (see Example 2 at cols. 4 and 5). Thus, Oyama clearly

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administers the claimed ingredient to exactly the category of patient disclosed by applicant as being the desired recipient of this treatment. It is therefore respectfully submitted that the rejection of record must be maintained.

Lastly, note specifically that all of the compositions of the cited references are clearly encompassed by product claim 18.

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing



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date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.C. Prats whose telephone number is (703) 308-3665.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael G. Wityshyn, can be reached on (703) 308-4743.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Communications applicant wishes to submit by FAX should be submitted to FAX # (703) 305-4242 or (703) 305-3014.



FRANCISCO C. PRATS  
PRIMARY EXAMINER  
ART UNIT 1651

F.C. Prats  
April 3, 2000